Remarks

In the Claims

Claims 26, 27, 29-42, 44-50, 52-65 and 67-71 are currently pending in the application. As discussed in greater detail below, Applicant has amended claim 71 in response to an objection by the Office. No new matter has been added.

Claim Objections

The Office Action of April 13, 2011 objected to claim 71 for not having a period at the end of the claim. This has been corrected. In addition, claims 45-48, 68 and 71 have been found to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Although this determination by the Office is appreciated, Applicant continues to believe that all of the pending claims are patentable over the art of record.

Rejection under 35 U.S.C. §102

The Office Action rejected claims 26-27, 30-31, 33-36, 38-40, 41-42, 44, 49-50, 53-65 and 69-70 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,070,761 issued to Bloom et al. ("Bloom"). Applicant respectfully traverses.

The independent claims 26 and 49 recite at least one feature that is neither anticipated nor rendered obvious by Bloom. For example, claim 26 recites a container spiking assembly controller in communication with the container spiking assembly for controlling coupling of the container receptacle with the port assembly, wherein the container spiking assembly controller is configured to control the movement of the movable member of the container spiking assembly to couple the container receptacle with the port assembly while the port assembly is immobilized relative to the container receptacle. Claim 49 recites a coupling means for controlling coupling of the container receptacle with the port assembly, the specification clearly describing how this may be accomplished.

The Office Action alleges that Bloom discloses a container spiking assembly controller as recited in the pending claims, citing col. 15-16 and Figures 7 and 13 of Bloom, and referring to items 77, 118, 206 and 304. First, the Office Action admits in its review of Bloom that the

pressure conduction chambers of cassette 77 are operated on by positive and negative pneumatic pressure by fluid delivery module 88 to perform **reconstitution, dilution and metering** of the medication. Control and management module 304 determines the appropriate admixture process to be followed for the subject medication and controls fluid delivery module 88 to **reconstitute and/or dilute** the medication as determined. Control and management module 304 also controls delivery of the medication to the patient. However, the Office Action fails to identify where in Bloom a controller or module is disclosed to be involved in controlling the movement of a movable member of a container spiking assembly. The Office Action refers to sensors associated with an outer and inner door behind which a cassette is placed, but this does not constitute a movable member of a container spiking assembly, much less one under the control of a controller. Bloom cannot therefore anticipate the independent claims – and by extension the dependent claims – of the instant application. Withdrawal of the rejections under 35 U.S.C. §102(b) is requested.

Rejection under 35 U.S.C. §103

(1) The Office Action also rejected claims 26-27, 30-31, 33-36, 38-40, 41-42, 44, 49-50, 53-65 and 69-70 under 35 U.S.C. §103(a) as being obvious over Bloom. Applicant disagrees.

The Office Action has not established a prima facie case that Bloom renders the pending claims obvious. For example, the vial loading mechanism disclosed in Bloom provides a specific means of securing a vial to the vial holder 207 that is not readily amenable to automation (i.e., under control of a controller). As the Office Action notes, Bloom discloses a cassette 77 having a midbody 113 to which spikes 118 are welded. According to Bloom, the membrane seals 120 of vials 85 are pierced by a clinician inverting each vial 85 and lowering the vial 85 onto the spike 118 so as to pierce seal 120 with spike 118. (Bloom, col. 18, ll. 16-20). The clinician forces the holder 207 to be lowered so that the spike 118 pierces the membrane seal 120 of the vial 85. (col. 19, ll. 38-41). Note that the cutout 222 allows the head of a vial 85 to fit into the arcuate holding portion 216, with the tang 218 supporting the head of the vial 85 (Fig. 12 and col. 18 ll. 37-43). Thus, the entire vial or container is held in place on the vial loading mechanism through contact at the neck of the vial. The structure and arrangement of the vial

loading mechanism of Bloom is clearly designed for a clinician to be involved in "lowering the vial 85 onto the spike 118." Thus, Bloom does not disclose, teach, suggest or provide any guidance on constructing a controller-mediated movable member of a container spiking assembly.

In contrast, claim 26 of the instant application recites a controller for controlling the movement of a movable member of a container spiking assembly to couple a container receptacle with a port assembly. There is no indication in Bloom how one of ordinary skill could incorporate such a feature into the device disclosed, for example, in Figs. 12 and 13. An assertion of prima facie obviousness may not be maintained by simply arguing in hindsight that the claims of the instant application are rendered obvious by some unspecified modification of the vial loading mechanism disclosed in Bloom. The Office has not demonstrated that Applicant's invention is: (a) a combining of prior art elements according to known methods to yield predictable results; (b) a simple substitution of one known element for another to obtain predictable results; (c) use of a known technique to improve similar devices in the same way; or (d) applying a known technique to a known device ready for improvement to yield predictable results (see MPEP §2143). Therefore, because the pending claims are not obvious over Bloom, withdrawal of the rejections under 35 U.S.C. §103(a) is requested.

(2) In addition, the Office Action separately rejected claims 29, 32, 37, 52 and 67 under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,070,761 issued to Bloom et al. ("Bloom"). Applicant respectfully disagrees.

Arriving at the invention claimed in the instant application is not merely a matter of adding sensors and logic to the device disclosed in Bloom. The Office Action alleges that Bloom teaches "complete automation of the apparatus for mixing a substance in a sealed container with a liquid," and that Bloom teaches "sensors/logic to detect and control movement." The Office Action states that one of ordinary skill in the art would have been motivated to use logic and sensors to control the positioning of the vials, cover locks and spiking assembly based on the teachings of Bloom, referring to cols. 21-26 of Bloom. First, it has not been shown where in Bloom there is disclosure of sensors and logic to control movement of anything other than the fluids being pumped within the cassette. And regarding the use of a controller to control a

container spiking assembly, the manner in which a vial is held on the device disclosed in Bloom (i.e., by the neck of the vial, as discussed above) precludes any simple or straightforward modification to achieve automated spiking. Without a clear pathway to achieving this type of automation, there can be no reasonable expectation of success. Therefore, because the pending claims are not obvious over Bloom, withdrawal of the rejections under 35 U.S.C. §103(a) is requested.

Conclusion

For the foregoing reasons all of the claims of the present invention are patentable over the art of record. It is believed that all of the claim rejections have been addressed and that the application is in condition for allowance. Reconsideration of the claims and issuance of a notice of allowance are respectfully requested. If any matter arises for which an interview may expedite issuance of a notice of allowance, the Examiner is requested to call the undersigned at the telephone number given below.

Applicant believes that a 3-month extension of time is required, and requests that the associated extension fee be charged to Deposit Account No. 50-4383. Applicant also requests that any other fee required for timely consideration of this application be charged to Deposit Account No. 50-4383.

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Respectfully submitted,

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